IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: T. JERUSSI

Application No.: To be assigned

(Division of U.S. Application No. 10/278,097)

Group Art Unit: To be assigned

Filed: Herewith Examiner: To be assigned

For: METHODS OF TREATING AND PREVENTING Attorn

NARCOLEPSY USING ENANTIOMERICALLY PURE (S)-DIDESMETHYLSIBUTRAMINE

(As amended)

Attorney Docket No.: 4821-529-999

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and §1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby direct the Examiner's attention to 142 references (AA-FL) listed on the attached form PTO-1449 entitled "List of References Cited by Applicant."

Identification of the foregoing references is not to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use Form PTO-1449, since that form identifies all of the references cited therein as "Prior Art." As an alternative, Applicants submit herewith a "revised Form PTO-1449" entitled "List of References Cited."

Applicants request that the Examiner review all the references identified on the attached List of References Cited, and that they be made of record in the file history of the above-identified application. No fee is believed to be due for this submission since it is being made prior to a first Office Action on the merits in the above case. Should any fees be required, however, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date: Mr. 21, 2003

lac Jahan 45,479

(Reg. No.)

PENNIE & EDMONDS LLP

1667 K Street, N.W. Washington, DC 20006

(202) 496-4400

For: Anthony M. Insogna

(Reg. No. 35,203)

PENNIE & EDMONDS LLP 12750 High Bluff Drive, Suite 300

San Diego, CA 92130 (858) 314-1200

Enclosures

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. APPLICATION NO.			
4821-529-999	Not yet assigned		
APPLICANT			
T. Jerussi			
FILING DATE	GROUP		
Herewith	To be assigned		

		T	<u>U</u>	S. PATENT DOCUMENTS	<u> </u>		
*EXAMINER INITIAL	<u> </u>	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIAT
	AA	6,127,363	10/2000	Doherty et al.			ļ
	AB	6,174,925	01/2001	Bailey et al.			
	AC	6,046,242	11/1998	Emmelmann			
	AD	5,795,880	08/1998	Svec et al.			
	AE	5,780,051	07/1998	Eswara et al.			
	AF	5,733,566	03/1998	Lewis	·		
	AG	5,719,283	02/1998	Bell et al.			
	АН	5,674,553	10/1997	Shinoda et al.			
	Al	5,639,476	06/1997	Oshlack et al.			
	AJ	5,591,767	01/1997	Mohr et al.			
	AK	5,552,429	09/1996	Wong et al.		L	
	AL	5,459,164	10/1995	Vargas			
	АМ	5,436,272	07/1995	Scheinbaum			
	AN	5,354,556	10/1994	Sparks et al.			
1.4.	AO	5,250,534	10/1993	Bell et al.			
	AP	5,120,548	06/1992	McClelland et al.			
 -	AQ	5,104,899	04/1992	Young et al.			
	AR	5,073,543	12/1991	Marshall et al.			
	AS	5,068,440	11/1991	Jeffery et al.			
	АТ	5,059,595	10/1991	Le Grazie			
	ΑU	4,988,814	01/1991	Abou-Gharbia et al.			
	AV	4,939,175	07/1990	Ukai et al.			
	AW	4,929,629	05/1990	Jeffery			
	AX	4,871,774	10/1989	Rees			
	AY	4,816,488	03/1989	Rees			
	AZ	4,814,352	03/1989	Jeffery et al.			
	ва	4,806,570	02/1989	Jeffery et al.			
	вв	4,746,680	05/1988	Jeffery et al.			
	вс	4,552,828	11/1985	Toya et al.			
	BD	4,522,828	06/1985	Jeffery et al.			
	BE	4,008,719	02/1977	Theeuwes et al.			
	BF	3,960,891	06/1976	Malen et al.			

•	,		I	L				
	BG	3,916,899	11/1975	Theeuwes et al.			-	
	вн	3,845,770	11/1974	Theeuwes et al.			 	
	ВІ	3,598,123	08/1971	Zaffaroni			ļ	
	BJ	3,536,809	10/1970	Applezweig			ļ	
	вк	3,471,515	10/1969	Troxler et al.			<u> </u>	
	BL	3,155,670	11/1964	Janssen et al.	_		ļ	
	ВМ	3,155,669	11/1964	Janssen et al.				
		ſ	FORE	IGN PATENT DOCUMENTS				
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLA YES	NO NO
	BN	WO 00/56322	09/2000	PCT			120	,,,,
	ВО	WO 00/56321	09/2000	PCT				
	BP	WO 00/56318	09/2000	PCT				
	BQ	WO 00/56315	09/2000	PCT				
	BR	WO 00/56314	09/2000	PCT				
	BS	WO 00/56309	09/2000	PCT				
	вт	WO 00/56306	09/2000	PCT				
	BU	WO 00/56151	09/2000	PCT				
	BV	WO 00/56150	09/2000	PCT				
	вw	WO 00/56149	09/2000	PCT				
	вх	WO 00/56148	09/2000	PCT				
	BY	WO 00/54765	09/2000	PCT				
	BZ	WO 00/32182	11/1998	PCT				
	CA	WO 99/33450	07/1999	PCT				
	СВ	WO 98/13034	04/1998	PCT				
	СС	WO 98/13033	04/1998	PCT				
	CD	WO 98/11884	03/1998	PCT				
	CE	WO 98/06722	02/1998	PCT				
	CF	EP 0 781 561 A1	07/1997	EPO				
	CG	WO 97/20810	06/1997	РСТ			·-	
	СН	WO 97/03675	02/1997	РСТ				
	СІ	WO 95/21615	08/1995	PCT				
	Cl	WO 95/20949	08/1995	PCT				
	ск	WO 94/28902	12/1994	РСТ				
	CL	WO 94/00114	01/1994	РСТ				
	СМ	WO 94/00047	01/1994	РСТ				
	CN	WO 90/06110	06/1990	РСТ				
	со	WO 88/06444	09/1988	РСТ				
<u> </u>	СР	DE 32 12 682 A1	10/1982	Germany				
	CQ	GB 2098602 A	11/1982	United Kingdom				

.,	CR	EP 0 035 597	9/1981	Europe						
		OTHER RE	FERENCES (//	ncluding Author, Title, Date, Pertinent Pages, Etc)					
	CS Baldessarini et al., <i>Life Sciences</i> 39 : 1765-1777, (1986).									
	СТ	Buckett et al., "BTS 54 524-An Approach to Rapidly Acting Antidepressant," New Concepts in Depression 2: 167-172 (1988).								
	cu		Bucket et al., "The Pharmacology of Sibutramine Hydrochloride (BTS 54 524), A New Antidepressant which induces Rapid Noradrenergic Down-Regulation", <i>Prog. Neuro-Psychopharmacol. & Biol. Psychiat.</i> 12 : 575-584 (1988).							
	cv	Buckett et al., "Sibutra	mine Hydroc	hloride," Drugs of the Future 13(8): 736-7	88 (1988)					
-	cw	Butler, D., Facile Cyclo	alkylation of A	Arylacetonitriles in Dimethyl Sulfoxide, J. O	g. Chem	., 36:1308-	1309 (1	971)		
	сх	Canonne, P., et al., <i>Efi</i> 21:155-58 (1980)	fet du Benzei	ne Dans la Reaction de Grignard sur les l	litriles, Te	etrahedron	Lett.,	_		
	CY	Carstensen, J., Drug S	Stability: Prin	ciples & Practice, 2d. Ed., pp. 379-80, Ma	rcel Dekl	ker, NY, N	Y, (1995	5).		
	cz	Castello, R.A., et al., (1962)	Discoloration	of Tablets Containing Amines and Lacte	se, Phar	m. Sci. 51	(2):106	-108 —		
	DA		Cheetham, S.C., et al., [³ H]Paroxetine Binding in Rat Frontal Cortex Strongly Correlates with [³ H]5-HT Uptake: Effect of Administration of Various Antidepressant Treatments, Neuropharmacology (1993), 32(8),							
	DB			methoxyphenyl)-piperazin-1-yl)-2-phenylp tic and Postsynaptic 5-HT _{1A} Receptors, Me						
	DC	Diagnostic and Statisti (1997).	cal Manual o	f Mental Disorders, Fourth Ed., American	Psychiati	ric Associa	ition,			
	DD	Diagnostic and Statisti	cal Manual o	f Mental Disorders, 3rd Ed., American Ps	chiatric A	Association	า (1981)).		
	DE			Fluoxetine-Dependent Increase of Extrace HT _{1A} Receptors, Neurochem. Res., 21(5):			IT) Leve	els		
	DF	Eliel, E.L., Stereochem	nistry of Carb	on Compounds (McGraw-Hill, NY, 1962).						
	DG	Evans et al., "Prevaler 262: 2551-2556 (1989)		mer's Disease in a Community Population	of Older	Persons,"	J.A.M.A	١.		
·	DH			e apparent anti-depressant activity of (-) a , 85 : 7, page 31, No. 40768t (1976).	ınd (+) tra	anylpromin	e in an			
	DI	Goodman & Gilman, T	he Pharmaco	ological Basis of Therapeutics, 362-373, 4	04 (9 th ec	I. McGraw	-Hill, 19	96)		
_	DJ	Gray et al., The Involve Antidepressant Compo	ement of the ounds, BR.J.	Opioidergic System in the Antinociceptive Pharmacol., Vol. 124, No. 4, (1998) pp 66	Mechani 9-674	ism of Acti	on of			
	DK			ients, 2 nd ed., Wade and Willer eds., pp. 2		1994)				
	DL			fects on Central 5-HT Function of Sibutrar armacol. (1998), 125(2), 301-308	nine Hydi	rochloride	and Oth	her		
	DM	Hillver et al., (S)-5-Fluc Med. Chem., 33:1541-		y-2-(dipropylamino)tetralix: A Putative 5-F	T _{1A} Rece	ptor Antag	onist, J	١.		
	DN	J. Med. Chem., Vol. 36		40 (1993)						
	DO	Introduction to Pharma	ceutical Dos	age Forms, 4th ed., Lea & Febiger, Philac	elphia (1	985).				
	DP	Jacques et al., "Enantion	omers, Race	mates and Resolutions," (Wiley-Interscier	ce, NY, 1	1981).				
	DQ	Jamali et al., <i>Journal</i> o	f Pharmaceu	tical Sciences, 78 : 9: 695-715 (1989)						
	DR			nine, A Novel Cyclobutylalkylamine Useful . Chem. Soc. Perkin. Trans. 1, 2583-2589		eatment of	Obesit	у,		

•		
. •	DS	King et al., "Clinical Pharmacology of Sibutramine Hydrochloride (BTS 54524) A New Antidepressant, in Healthy Volunteers," <i>Clinical Pharmac.</i> 26 : 607-611 (1989).
	DT	Kula et al., "Effects of N-Substituted Phenyltetrahydropyridines on Cerebral High-Affinity Synatosomal Uptake of Dopamine and Other Monoamines in Several Mammalian Species," Life Sciences 34 (26): 2567-2575, (1984).
	DU	Luscombe et al., The Contribution of Metabolites to the Rapid and Potent Down-Regulation of Rat Cortical β-Adrenoceptors by the Putative Antidepressant Sibutramine Hydrochloride, Neuropharmacology, Vol. 28, No. 2, (1989) pp 129-134
	DV	The Merck Manual of Diagnosis and Therapy, ??th Ed., Merck & Co., Inc., Whitehouse Station, NJ, (1999).
	DW	Middlemiss et al., Centrally Active 5-HT Receptor Agonists and Antagonists, Neurosci. and Biobehv. Rev., 16:75-82 (1992)
	DX	Moreau et al., Behavioral Profile of the 5-HT _{1A} Receptor Antagonist (S)-UH-301 in Rodents and Monkeys, Brain Res. Bull., 29:901-04 (1992)
	DY	Nakada et al., An Enantioconvergent Route to (-)-Kainic Acid, Tetrahedron Lett., 38:857-860 (1997)
	DZ	Physician's Desk Reference® 473-475 (53 rd ed., 1999)
	EA	Physician's Desk Reference® 475-476 (53 rd ed., 1999)
	EB	Physician's Desk Reference® 764-766 (53 rd ed., 1999)
	EC	Physician's Desk Reference® 823-825 (53 rd ed., 1999)
	ED	Physician's Desk Reference® 978-979 (53 rd ed., 1999)
	EE	Physician's Desk Reference® 1054-1056 (53 rd ed., 1999)
	EF	Physician's Desk Reference® 1332-1334 (53 rd ed., 1999)
	EG	Physician's Desk Reference® 1369-1370 (53 rd ed., 1999)
	EH	Physician's Desk Reference® 1432-1436 (53 rd ed., 1999)
	EI	Physician's Desk Reference® 1494-1498 (53 rd ed., 1999)
	EJ	Physician's Desk Reference® 1641-1645 (53 rd ed., 1999)
	EK	Physician's Desk Reference® 2004-2009 (53 rd ed., 1999)
	EL	Physician's Desk Reference® 2075-2078 (53 rd ed., 1999)
<u></u>	ЕМ	Physician's Desk Reference® 2190-2192 (53 rd ed., 1999)
	EN	Physician's Desk Reference® 2367-2368 (53 rd ed., 1999)
	EO	Physician's Desk Reference® 2396-2399 (53 rd ed., 1999)
	EP	Physician's Desk Reference® 2490-2493 (53 rd ed., 1999)
	EQ	Physician's Desk Reference® 2516-2521 (53 rd ed., 1999)
	ER	Physician's Desk Reference® 2688-2691 (53 rd ed., 1999)
	ES	Physician's Desk Reference® 2701-2704 (53 rd ed., 1999)
	ET	Physician's Desk Reference® 2720-2726 (53 rd ed., 1999)
	EU	Physician's Desk Reference® 2735-2736 (53 rd ed., 1999)
	EV	Physician's Desk Reference® 2886-2888 (53 rd ed., 1999)
	EW	Physician's Desk Reference® 2908-2910 (53 rd ed., 1999)
	EX	Physician's Desk Reference® 3092-3094 (53 rd ed., 1999)
	EY	Physician's Desk Reference® 3101-3104 (53 rd ed., 1999)

EXAMINE	R	DATE CONSIDERED
	FL	Wilen, S.H., <i>Tables of Resolving Agents and Optical Resolutions</i> 268 (E.L. Eliel ed., Univ. of Notre Dame Press, Notre Dame, IN, 1972).
	FK	Wilen et al., <i>Tetrahedron</i> , 2725-36 33 (21) (1977).
	FJ	U.S. Pharmocopia (USP) SP (XXI)/NF (XVI)
·	FI	Stock, M.J., Sibutramine: A Review of the Pharmacology of a Novel Anti-Obesity Agent, Int'l J. Obesity, 21(Supp. 1):S25-S29 (1997)
<u> </u>	FH	Remington's Pharmaceutical Sciences, 16th ed., Mack Publishing, Easton PA (1980).
	FG	Remington's Pharmaceutical Sciences, 18th ed., Mack Publishing, Easton PA (1990).
	FF	Remingtons: The Practice of TheScience and Pharmacy, 19 th ed., Gennaro, ed., p. 1625 (1995)
	FE	Physician's Desk Reference® 2958 (52 nd ed., 1998)
	FD	Physician's Desk Reference® 2520 (52 nd ed., 1998)
	FC	Physician's Desk Reference® 3383-3384 (53 rd ed., 1999)
	FB	Physician's Desk Reference® 3307-3309 (53 rd ed., 1999)
	FA	Physician's Desk Reference® 3267-3272 (53 rd ed., 1999)
y .	EZ	Physician's Desk Reference® 3224-3225 (53rd ed., 1999)

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.